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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,876	10/19/2001	Steven M. Ruben	PZ001G67AP1D1	8845

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M.

Office Action Summary	Application No.	Applicant(s)	
	09/981,876	RUBEN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-9, 12-18, 21-32 and 35-37* is/are allowed.

6)☒ Claim(s) *10,11,19,20,33,34 and 38-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 6/14/04, is acknowledged.

2. Claims 1-74 are pending and under examination.

3. In view of the amendment filed on 6/14/04, only the following rejections are remained.

4. Claims 10-11, 19-20, 33-34, 47, 56 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons set forth in the previous Office Action mailed 3/11/04.

Claims 10-11, 19-20, 33-34, 47, 56 and 70 have no antecedent basis in base claims 1, 15, 24, 38, 52 and 61, respectively, because claims 1, 24 recite antibody or fragment thereof per se, whereas a labeled antibody or fragment thereof is recited in claims 10. It is suggested that claim 10, for example, be changed to "A labeled antibody or portion thereof, wherein the antibody or fragment thereof of claim (1) is labeled" and dependent claims thereof be changed to "The labeled antibody or fragment thereof of claim ...".

It is noted that Applicant has not addressed the issue.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 38-74 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation for the same reasons set forth in the previous Office Action mailed 3/11/04.

7. The polypeptide encoded by the HRGDF73 cDNA contained in ATCC deposit Number 97904 recited in claims 38, 52 and 61 are essential to the claimed invention. The specification on page 121, paragraph 404, discloses that some of the deposits contain multiple different clones corresponding to the same gene, Table 1 on pages shows that ATTCC deposit No. 97904 contains the following cDNA Clone ID: HSATP28, HHFGL41, HBJEM49, HSLDJ95, HSREG44, HTXCT40, HRGDF73, HRDBF52, HKMND45, HPEBD70 and HMCAB89. Uni-ZAP XR is a vector contained in the cDNA Clone ID which contain the same antibiotic resistant for all the clones. The reproduction of the claimed polypeptide from the disclosed deposit No. 97904 is an extremely unpredictable event because it is known that bacteria contain multiple different clones with the same antibiotic resistant would lead to selective pressure favoring some

clones over others and there is no guarantee that the HRGDF73 cDNA encoding the polypeptide of SEQ ID NO: 200 is going to be selected over time. The vector, Uni-XAP XR comprising the HRGDF73 cDNA encoding the polypeptide of SEQ ID NO: 200, disclosed in table 1, page 119, 2nd row of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the vector, and it is not apparent if the vector is readily available to the public.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the vector has been deposited under the Budapest Treaty and that the vector will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer.* See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the vector described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's arguments, filed 6/14/04, have been fully considered, but have not been found convincing.

Applicant's statement filed on 6/14/04, is sufficient to overcome the previous rejection of the instant claims based upon the deposit of biological materials under 35 U.S.C. § 112, first paragraph because the reproduction of the polypeptide from the disclosed deposit No. 97904 is an extremely unpredictable event because it is known that bacteria contain multiple different clones with the same antibiotic resistant would lead to selective pressure favoring some clones over others and there is no guarantee that the HRGDF73 cDNA encoding the polypeptide of SEQ ID NO: 200 is going to be selected over time. The vector, Uni-XAP XR comprising the HRGDF73 cDNA encoding the polypeptide of SEQ ID NO: 200, disclosed in table 1, page 119, 2nd row of the specification, must be obtainable by a repeatable method set forth in the

specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the vector.

11. Furthermore, besides an isolated polypeptide comprising SEQ ID NO: 200 and the amino acid 25-123 of SEQ ID NO: 200 the specification fails to provide any guidance as to how to make an isolated antibody or portion thereof that specifically binds to a protein whose sequence consists of the amino acid sequence of the secreted polypeptide encoded by "the HDGRF73 cDNA contained in ATCC Deposit Number 979004" in claim 38, or an isolated antibody produced by immunizing an animal with a protein whose sequence comprises the amino acid sequence of the secreted polypeptide encoded by "the HDGRF73 cDNA contained in ATCC Deposit Number 97904", wherein said antibody or portion thereof specifically binds to the polypeptide encoded by "the HDGRF73 cDNA contained in ATCC Deposit Number 97904" in claim 52, or an isolated antibody or portion thereof that specifically binds to a protein whose sequence consists of the amino acid sequence of the full-length polypeptide encoded by "the HDGRF73 cDNA contained in ATCC Deposit Number 97904" in claim 61. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The ATCC deposit No. 97904 contains multiple different clones. It is recognized in the prior art that the multiple insertions in the same strain are only limited by the availability of distinct selection markers. Given the lack of marker specific for SEQ ID NO: 200, the claimed antibody is not specific for SEQ ID NO: 200 but the antibody would be raised against (bind to) multiple different proteins encoded by the multiple different cDNA contained in ATCC Deposit No. 97904. Further, the reproduction of the polypeptides from the disclosed deposit No. 97904 is an extremely unpredictable event because it is known that bacteria contain multiple different clones with the same antibiotic resistant would lead to selective pressure favoring some clones over others and there is no guarantee that the HDGRF73 cDNA encoding the polypeptide of SEQ ID NO: 200 is going to be selected over time.

Applicant's arguments, filed 6/14/04, have been fully considered, but have not been found convincing.

The Examiner is confused by the Applicant's confusion over the rejection that a specific marker from the claimed protein is not provided. The previous rejection mailed on 3/11/04, specifically states the ATCC deposit NO. 97904 contains multiple different clones and that the multiple insertions in the same strain are only limited by the availability of distinct selective markers (i.e., an antibiotic selectable **marker** gene). Further, it is known that bacteria contain multiple different clones with the same antibiotic resistant would lead to selective pressure favoring some clones over others and there is no guarantee that the cDNA encoding the polypeptide of SEQ ID NO: 200 is going to be selected over time. It is unclear to the examiner what is confusing about "specific marker" (i.e. specific antibiotic selectable marker).

Applicant submits that the amino acid sequence of SEQ ID NO:200 and/or a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO: 200, which are provided in the

Sequence listing and correlated to Clone ID HDGRF73 in Table 1(page 119), can be used by a skilled artisan to as a specific marker" to select clones containing the claimed HDGRF73 cDNA. For example, one of ordinary skill in the art could have employed either of the methods described in Example 1 of the specification (page 159) to the isolated a cDNA of interest. Applicant continue to explain that by transforming the DNA contained within ATCC Deposit No. 97904 into host cells, one of ordinary skill in the art could generate a population of isolated colonies each containing a particular cDNA plasmid. Applicant contends that following transformation, screening with an oligonucleotide complementary to the DNA encoding SEQ ID NO: 200 would enable easy identification of the isolated transformat(s) containing the cDNA plasmid of interest. Applicant submits that the fact that "bacteria contain multiple different clones with the same antibiotic resistant" does not render reproduction of the polypeptides from the deposit extremely unpredictable.

Applicant's attempts to provide a process to obtain HDGRF73 CDNA rather that provide "specific marker" for HDGRF73 is inconsistent with the well-known and art-recognized selective marker of the gene of interest with specific antibiotic resistant gene. That is the multiple insertions in the same strain are only limited by the availability of distinct selection markers. Further, the process of obtaining HDGRF73 cDAN for the clone does not address the concern that the lack of antibiotic marker for HDGRF73 cDNA would lead to selective pressure favoring some clones over others and there is no guarantee that the HDGRF73 cDNA is going to be selected over time because the different multiple clones contain the same selective antibiotic marker. Applicant's method would only lead to the isolation of the HDGRF73 cDNA in clones already have the HDGRF73 cDNA. However, the issue is whether those clone continue to have HDGRF73 because of lack of antibiotic selective marker for the HDGRF73 cDNA.

8. Claims 38-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action mailed 3/11/04.

Applicant's arguments, filed 6/14/04, have been fully considered, but have not been found convincing.

Applicant is in possession of an antibody or portion thereof that specifically binds to a protein whose sequence consists of amino acid residues 25 to 123 of SEQ ID NO: 200, or an isolated antibody or portion thereof that specifically binds to a portion whose sequence consists of amino acid residues 1 to 123 of SEQ ID NO: 200.

Applicant is not in possession of any isolated antibody or portion thereof that specifically binds to a protein whose sequence consists of the amino acid sequence of the secreted polypeptide encoded by "the cDNA contained in ATCC Deposit Number 979004" in claim 38, or an isolated antibody produced by immunizing an animal with a protein whose sequence comprises the

amino acid sequence of the secreted polypeptide encoded by "the cDNA contained in ATCC Deposit Number 97904", wherein said antibody or protion thereof specifically binds to the polypeptide encoded by "the cDNA contained in ATCC Deposit Number 97904" in claim 52, or an isolated antibody or portion thereof that specifically binds to aprotein whose sequence consists of the amino acid sequence of the full-length polypeptide encoded by "the cDNA contained in ATCC Deposit Number 97904" in claim 61.

Applicant submits that the amendments to the claims overcome this rejection. Specifically, claims 38, 52, and 61 have been amended to refer to HRGDF73 cDNA contained in ATCC Deposit NO. 97904.

However, there is no described or art-recognized correlation or relationship between the structure of the invention, the HRGDF73 cDNA contained in the ATCC Deposit No. 97904 and it's function, the feature deemed essential to the instant invention. Therefore, one of skill in the art would not envisage, based on the instant disclosure, the claimed HRGDF73 cDNA, which retain the features essential to the instant invention.

9. Claims 1-9, 12-18, 21-32 and 35-37 are allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
July 26, 2004

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